

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

	APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,039			12/11/2003	John Charles Kath	PC25339A	8724
		7590	06/28/2006		EXAMINER	
	PFIZER IN	. •			BALASUBRAMANIAN, VENKATARAMAN	
	150 EAST 4	2ND STR	EET			
	5TH FLOOR - STOP 49				ART UNIT	PAPER NUMBER
	NEW YORK, NY 10017-5612				1624	· · · · · · · · · · · · · · · · · · ·

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)					
		10/734,039	KATH ET AL.					
	Office Action Summary	Examiner	Art Unit					
		Venkataraman Balasubramanian	1624					
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status		,						
1)⊠	Responsive to communication(s) filed on <u>07 Ap</u>	oril 2006.						
-	•	action is non-final.						
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims							
4)⊠	Claim(s) 1-24,31 and 32 is/are pending in the a	application.						
•	4a) Of the above claim(s) is/are withdrawn from consideration.							
	5) Claim(s) is/are allowed.							
6)⊠	6)⊠ Claim(s) <u>1-24, 31 and 32</u> is/are rejected.							
7)	7) Claim(s) is/are objected to.							
8)	Claim(s) are subject to restriction and/or	r election requirement.						
Applicati	on Papers							
9)□	The specification is objected to by the Examine	r.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority u	inder 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:								
1. Certified copies of the priority documents have been received.								
2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage								
application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
Attachmen								
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da						
3) Inform	e of Draftsperson's Patent Drawing Review (P10-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date		Patent Application (PTO-152)					

Art Unit: 1624

DETAILED ACTION

Applicants' response, which included addition of new claims31 and 32, cancellation of claims 25-30 and amendment to claims 1, 6-20 and 24, filed on 4/7/2006, is made of record. Claims 1-24, 31 and 32 are now pending.

In view of applicants' response, all 112 first and second paragraph rejections made in the previous office action have been obviated or rendered moot. However, the following rejections made in the previous office action are maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-23 and 25-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Dahmann et al., US2003/0171359.

Dahmann et al. teaches several 2,4-substitutedaminopyrimidine compounds for treating abnormal cell growth, which includes instant compounds. See pages 1-5, formula 1 and note the definition of various variable groups R^a, R^b, R^c, R^d and R^e. Especially note with the given definition of R^a, R^b, R^c, R^d and R^e, compounds taught by Dahmann et al. include instant compounds. See entire document for further details. See

Art Unit: 1624

pages 23-86 for large number of examples of compounds made. Note claims 25-30 are rejected as method of use of Dahmann et al. include breast cancer.

In view of applicants' response, this rejection has been deemed as obviated or rendered moot.

Claims 1-9 and 11-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Bornemann et al., US2005/0009853.

Bornemann et al. teaches several 2,4-substitutedaminopyrimidine compounds for treating illness due β-amyloid which include instant compounds. See pages 1-10, formula 1 and note the definition of various variable groups R^a, R^b, R^c, R^d and R^e. Especially note with the given definition of R^a, R^b, R^c, R^d and R^e, compounds taught by Bornemann et al. include instant compounds. See entire document for further details. See pages 18-25 for examples of compounds made. Especially see example 1, compound 43, 60, 70 and example 2, compound 16.

In view of applicants' response, this rejection has been deemed as obviated or rendered moot.

Claims 1-23, 31 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Nagarathnam et al., WO 03/030909 for reasons of record. To repeat:

Nagarathnam et al. teaches several 2,4-substitutedaminopyrimidine compounds for treating viral infection and cancer, which include instant compounds. See pages 3-10, formula 1 and note the definition of various variable groups X, R² and R³. Especially note with the given definition of X, R² and R³, compounds taught by Nagarathnam et al. include instant compounds. See entire document for further details. See pages 27-87

Art Unit: 1624

including Table 1-3 for large number of examples of compounds made. Note claims 25-30 are rejected as method of use of Nagarathnam et al. include breast cancer.

This rejection is same as made in the previous office action and is now limited claims 1-23, 31 and 32.

Contrary to applicants' urging, Nagarathnam et al., teaches NH fused aryl or heteroaryl at 2-position of pyrimidine ring and the Y definition meets the –(CR²R³)_n requirement. See definition of X. See Table 4 and note R⁵ groups meet this requirement.

Hence this rejection is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1624

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahmann et al., US2003/0171359 for reasons of record. To repeat:

Teachings of Dahmann et al. as discussed in the above 102 rejection is incorporated herein. As noted above, Dahmann et al. teaches several 2,4 substitutedaminopyrimidine compounds for treating abnormal cell growth, which includes instant compounds. See pages 1-5, formula 1 and note the definition of various variable groups R^a, R^b, R^c, R^d and R^e. Especially note with the given definition of R^a, R^b, R^c, R^d and R^e, compounds taught by Dahmann et al. include instant compounds. See entire document for further details. See pages 23-86 for large number of examples of compounds made. Note claims 25-30 are rejected as method of use of Dahmann et al. include breast cancer.

Dahmann et al. differs form the instant claims in exemplifying only limited number of compounds of the genus claimed in page 1 for compound of formula I. However, Dahmann et al. teaches equivalency of those compounds taught in pages 23-86 with those generically recited in pages 1-5.

Art Unit: 1624

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Dahmann et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action now limited claims 1-23, 31 and 32. Applicants' traversal to overcome this rejection is not persuasive.

As acknowledged by applicants, Dahmann et al., teaches R^c-N-R^d group at 4-position of the pyrimidine ring, which include araalkyl for Rc, and an alkyl substituted with aryl or heteroaryl. Hence, instant A is NH, B is absent or B is NR⁶ and A is absent, the compounds embraced in the instant claims include compounds taught by Dahmann et al. Dahmann et al., teaches equivalency of the exemplified compounds with those generically claimed. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Dahmann et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

There is no hindsight analysis is required. One trained in the art can make whatever compounds embraced in the genus using the teaching of the exemplified compounds and expect the resultant compounds to have the use taught therein. This clearly true for instant genus which is also very large. As recite it implies that all the compounds of the instant genus would have the said utility and hence one trained in the art would make compounds of the instant genus abased on the exemplified compounds (about 265 compounds out of millions of compounds of the instant genus).

Claims 1-23 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornemann et al., US2003/0134838.

In view of applicants' response, this rejection has been deemed as obviated or rendered moot.

Claims 1-23, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagarathnam et al., WO 03/030909 for reasons of record.

Teachings of Nagarathnam et al. as discussed in the above 102 rejection is incorporated herein. As noted above, Nagarathnam et al. teaches several 2,4-substitutedaminopyrimidine compounds for treating viral infection and cancer, which include instant compounds. See pages 3-10, formula 1 and note the definition of various variable groups X, R² and R³. Especially note with the given definition of X, R² and R³, compounds taught by Nagarathnam et al. include instant compounds. See entire document for further details. See pages 27-87 including Table 1-3 for large number of examples of compounds made. Note claims 25-30 are rejected as method of use of Nagarathnam et al. include breast cancer.

Nagarathnam et al. differs form the instant claims in not exemplifying only all the compounds of the genus claimed in pages 3-10 for compound of formula I. However, Nagarathnam et al. teaches equivalency of those compounds taught in pages 27-87 with those generically recited in pages 3-10.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of

Art Unit: 1624

Nagarathnam et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action and is now limited claims 1-23, 31 and 32.

Contrary to applicants' urging, Nagarathnam et al., teaches NH fused aryl or heteroaryl at 2-position of pyrimidine ring and the Y definition meets the –(CR²R³)_n requirement. See definition of X. See Table 4 and note R⁵ groups meet this requirement. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Nagarathnam et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Hence this rejection is proper and is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24, 31 and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 10/733,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims are also embraced in the copending application 10/733,215. Note substituents in 2, 4 and 5 position of the instant claims overlap with those of the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-24, 31 and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 11/122,515. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims are also embraced in the copending application 11/122,515. Note the trifuloromethylpyrimidine with indol-2-one side chain attached through a NH embraced in the instant claims are claimed in the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-24, 31 and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 11/127,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter

Art Unit: 1624

embraced in the instant claims are also embraced in the copending application 11/127,676. Note substituents in 2, 4 and 5 position of the instant claims overlap with those of the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-24, 31 and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/124,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims are also embraced in the copending application 11/124,006. Note substituents in 2, 4 and 5 position of the instant claims overlap with those of the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-24, 31 and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 11/127,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims are also embraced in the copending application 11/127,809. Note substituents in 2, 4 and 5 position of the instant claims overlap with those of the copending application.

. . . .

Art Unit: 1624

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

All the above double patenting rejections are same as made in the previous office action except that they are now applied to currently pending claims. As noted above in each case, the subject matter embraced in the instant claims are also embraced in the copending applications. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of copending application and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above. Hence, these rejections are proper.

Applicants have differed addressing these double patenting issues. The instant claims would not be allowable till the double patenting issues are resolved.

Hence, these rejections are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Application/Control Number: 10/734,039 Page 12

Art Unit: 1624

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be

addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571)

272-0662. The examiner can normally be reached on Monday through Thursday from

8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is

James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for

the organization where this application or proceeding is assigned (571) 273-8300. Any

inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAG. Status

information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have guestions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-2 17-9197 (toll-free).

Ventzulasamn Bulisulsamanian Venkataraman Balasubramanian

6/23/2006